Remarks

The Examiner's withdrawal of the rejection of claims 1-10 and 13-17 under 35 U.S.C §102(a) as anticipated by U.S. Patent No. 6,444,647 to Robinson and of claims 1-9, 13, 14, 16 and 17 35 U.S.C §102(b) as anticipated by U. S. Patent No. 5,686,089 to Mitra is appreciated.

Amendment to the Specification

The specification has been amended to correct an obvious typographical error in the steroid component of Lotrisone.TM. Support for this amendment can be found in the specification at least at page 1, line 23.

Review of the File History

Prior to addressing the specific rejections set froth in the Office action, a review of the file history would be helpful. Applicants' response to the non-final Office action mailed September 21, 2005, included a declaration under 37 CFR § 1.132 by co-inventor Dr. Jay Goldstein. The examiner considered the Goldstein declaration in the Final Rejection, mailed March 23, 2006. Ultimately, an Appeal Brief was filed in which Dr. Goldstein's declaration was relied upon as evidence of non-obviousness and the examiner's reasoning why the declaration was insufficient was addressed. See, e.g., Appeal Brief, pages 13-15. The examiner subsequently reopened prosecution by issuing the current Office action.

While the current Office action also contains obviousness rejections, it fails to acknowledge or discuss Dr. Goldstein's declaration. This was error on the examiner's part. As stated in In re Hedges, 783 F.2d 1038, 1039, 228 USPQ 685, 686 (Fed. Cir. 1986):

> If a *prima facie* case is made in the fist instance, and if the applicant comes forward with reasonable rebuttal, whether buttressed by experiment, prior art references, or argument, the entire merits of the matter are to be reweighed. In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984).

Furthermore, the current Office action maintains anticipation rejections based upon Quigley and Shah for essentially the reasons set forth in the Final Rejection. The examiner has not answered the arguments set forth in the Appeal Brief that are relevant to these anticipation rejections. This is again error on the part of the examiner.

As a result, applicants are at a loss to understand why Quigley and Shah are still considered to be anticipatory references and why Dr. Goldstein's declaration is not a sufficient rebuttal of the continued obviousness rejections.

In considering the declaration of Dr. Goldstein, the examiner has pointed to several references in the cited art that are stated to note that ultra-high and high potency halogenated or fluorinated anti-inflammatory steroids cause serious side effects, and asserted that this is a teaching towards the claimed selection (despite being irrelevant to a novelty analysis). Final rejection, pages 8-9. However, the claims are not drawn solely to low to low-medium potency anti-inflammatory steroids but to the combination of the anti-inflammatory with an anti-fungal compound. The claimed formulations have two functions, one of which is to treat a fungal infection and the other of which is to diminish inflammation. The two act by different mechanisms, which may in fact work against each other. It is well known that by decreasing inflammation, one also decreases the anti-infective capabilities of the body. The data presented

by Dr. Goldstein establish that the claimed compositions are both safe and efficacious. No where has the examiner pointed to where one of ordinary skill in the art would expect the combination of this ***selection*** to be safe and efficacious, as opposed to a combination of a low potency hydrocortisone and antifungal or a high potency anti-inflammatory and antifungal. Indeed, the only disclosure in the prior art cited by the examiner refers to selection of the anti-inflammatory; not to the selection of the antifungal so that the two are together safe and efficacious. It is important to note that the prior art did not recognize that the selection of both the anti-inflammatory and the antifungal are required for efficacy.

As Dr. Goldstein's declaration establishes, many of the patients had previously been treated with strong anti-inflammatory steroids. Counter-intuitively, the stronger anti-inflammatory creates more inflammation, not less, and thinning of the skin. The data in Dr. Goldstein's declaration not only demonstrates the unexpected efficacy and lack of side effects of one non-halogenated steroidal anti-inflammatory, desonide, in combination with an antifungal but additional data is presented showing the same unexpected efficacy and lack of side effects for other members of the claimed class of low to low-mid potency steroidal anti-inflammatories. Members of the claimed class that have been shown to produce results comparable to a topical cream containing 0.05% desonide and 1% clotrimazole are:

Clotrimazole 1% cream with alclometasone dipropionate 0.05% cream applied twice daily;

Oxiconazole cream 1% with Hydrocortisone cream 2½% applied twice daily;

Econazole cream 1% with fluocinalone acetonide cream 0.01% applied twice daily; and

Econazole cream 1% with alclometasone dipropionate 0.05% applied twice daily.

This data is comparative data, since the patients were initially treated with high potency steroidal anti-inflammatories in combination with antifungal agents. The unexpected efficacy of the small class of claimed low to low-medium potency steroidal anti-inflammatories in combination with an antifungal could not have been predicted in view of the prior art, which, to the extent it provides any teaching other than a "grocery list of compounds", teaches away from using weaker anti-inflammatories.

As stated in In re O'Farrell, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) "Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious."

The examiner's comments that the prior art recognized that steroid anti-inflammatories caused fewer or lesser side effects than more potent steroid anti-inflammatories miss the point of applicants' discovery and the import of the data of Dr. Goldstein's declaration. Dr. Goldstein states "there was the risk that lower potency steroids would not be effective." Goldstein declaration, paragraph 3. Prior to the work described in this application, one of ordinary skill in the art might have thought it to have been obvious to try combinations of antifungal agents with low to low-medium steroid anti-inflammatories. But it remained for the present inventors to actually select and use combinations of antifungal agents with low to low-medium steroid anti-inflammatories and discover that such combinations would successfully treat the underlying

condition, even where treatments with more potent steroids were unsuccessful. Thus, the data in Dr. Goldstein's declaration provides an objective basis for concluding the subject matter of the claims is nonobvious.

The examiner should keep this analysis in mind as he reconsiders the prior art rejections of record. In this regard, arguments are made below that Shah and Quigley stated by the examiner to be anticipatory of claim 1 are in law and fact not. If the examiner is of the impression that Shah and Quigley might form the basis of an obviousness rejection, he must take into account all evidence of record, including the declaration of Dr. Goldstein in making that determination. In doing so, it is believed that the examiner will conclude on the basis of all the evidence that the claims are directed to nonobvious subject matter.

Rejection Under 35 U.S.C. §112, first paragraph-written description

Claim 1 was rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection.

Analysis

The first reason given by the examiner is that the phrase "low to low-medium potency steroidal anti-inflammatory" as used in claim 1 is new matter or lacks written descriptive support in the original disclosure of this application. Office Action, December 15, 2006 (OA), page 2-3. When this phrase is considered in the proper legal and factual context it will be seen that this aspect of the rejection lacks merit.

"The 'written description' requirement serves a teaching function, in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted). Another "purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [ ], [the applicant] was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (Vas-Cath, 935 F.2d at 1562-63, 19 USPQ2d at 1116), and it is the examiner's "initial burden [to] present[ ] evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims" (In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)).

"[A]pplicants have some flexibility in the 'mode selected for compliance' with the written description requirement" (University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896); it is well settled that actual reduction to practice is not necessary to satisfy the requirement (id., at 926, 69 USPQ2d at 1894). Whether the level of disclosure in the specification would have allowed one skilled in the art to recognize that the inventor invented

what is claimed is a question of fact. The USPTO has summarized a number of factors to be considered in making this determination; they include "the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention." Guidelines for Examination of Patent applications Under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement, 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001). "Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." Id.

The examiner acknowledges that the specification describes the use of a genus of topical steroids having low to medium potency. OA, page 3. Thus, the question is whether a person of skill in this art would understand that applicants were also in possession of the sub-genus of topical anti-inflammatory steroids set forth in claim 1, i.e., "low to low-medium." It is submitted that a person of skill in the art, after reading the original disclosure of this application, would recognize that applicants were in possession of the subject matter of claim 1 including the use of a "low to low-medium potency steroidal anti-inflammatory...."

First, description of the genus of low to medium steroidal anti-inflammatories necessarily describes the included sub-genus of low to low-medium steroidal anti-inflammatories. Furthermore, a person of skill in the art understood that potency of topical anti-inflammatory steroids is commonly described by way of a classification system. See, e.g., Chart, Potency of topical steroids, National Psoriasis Foundation (copy attached to "Declaration Under 37 CFR §

1.132" of Jay A. Goldstein, of record) (Chart). The Chart sets forth seven classes of topical steroids ranging from Class 1—Superpotent to Class 7-- least potent. Quigley also describes a similar seven class classification system for anti-inflammatory steroids. Id., column 4, line 55-column 6, line 51. Applicants used such a classification system in describing the present technology in the specification. See, e.g., page five, first paragraph ("Desonide is a class 6 nonfluorinated topical corticosteroid....").

The genus of low to medium potency topical steroids described at page 3 of the specification corresponds to a genus of Class 4—Mid-strength, Class 5—Lower mid-strength and Class 6—Mild topical steroids such as those described in the Chart. Thus, by describing this genus, applicants necessarily described the sub-genus of mild (Class 6) to low-medium (Class 5) that is included within the broader genus. That applicants chose the terms low and low-medium instead of other phraseology such as "mild" or "lower mid-strength" as used in the Chart is of no moment as a person of skill in this art understood that the terms are describing the same classes of topical steroids. Furthermore, given that one of the objects set forth for the present technology is to reduce side effects, a person of skill in the art would also understand the present technology includes the use of low to low-medium potency topical steroids.

In making this rejection the examiner points to the description of desoximetasone and mometasone in the specification and states that these steroids can be considered as high-medium and medium potency topical steroids respectively. OA, page 3. Presumably the examiner's latter statement is based upon the description of various steroid compositions in the Chart. However, in considering the specific formulations set forth in the various classes of the Chart, it

must be kept in mind that potency of a topical steroid is dependent not only on the specific steroid and amount used but also on how the steroid is formulated. See McCadden, column 4, lines 9-22. For example, the Chart indicates that the topical steroid betamethasone valerate can be used in an amount and formulated so that it can be a Class 6 (Valisone Lotion, 0.1%), Class 5 (Valisone Cream/Ointment, 0.1%) or Class 3 (Valisone Ointment 0.1%). The specification states that the topical formulations can be in various forms. Id., page 7. Thus, the fact that the Chart exemplifies the topical steroids desoximetasone and mometasone in formulations that are not of low to low-medium potency is of no moment since the record is clear that a person of skill in this art, reading the original disclosure of this application would understand that topical steroids can be formulated in a variety of ways to arrive at a desired potency such as low to low-medium as set forth in claim 1.

The examiner also considers the phrase "having a higher potency of 1 wt% hydrocortisone" to be new matter and lack written descriptive support in the original disclosure. OA, pages 3-4. The examiner acknowledges that the specification states that a composition of 1 wt% hydrocortisone would be minimally effective if at all. Id. The examiner goes on to state that "inadequate support exists in the specification as filed for amending the claim to recite…'having a higher potency than 1 wt% hydrocortisone.'" The examiner does not provide any support for this conclusion. The Chart states that topical steroid formulations with hydrocortisone are Class 7—Least potent. Thus, a person of skill in this art would understand that the class of low to low-medium steroids set forth in claim 1 have a higher potency than 1 wt% hydrocortisone and that the inventors were also in possession of this portion of claim 1.

Withdrawal of the rejection is courteously solicited.

Rejection Under 35 U.S.C. §112, second paragraph-indefiniteness

Claims 1-17 were rejected under 35 U.S.C. §112 as being indefinite. Applicants respectfully traverse this rejection.

Analysis

The examiner asserts that applicants have not clearly defined what constitutes a low-medium potency topical steroid. OA, page 5.

As set forth in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971) (footnote omitted) "the definiteness of the language [employed in a claim] must be analyzed—not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." Here, the examiner has read claim 1 in a vacuum and has not taken into account the pertinent teachings of the prior art and the specification.

As set forth above in responding to the examiner's written description rejection, the prior art understands the metes and bounds of the phrase "low-medium potency steroidal anti-inflammatory." See, e.g. the Chart. McCadden also provides evidence that the potency of a topical steroid composition depends upon the steroid, its amount and the manner in which the composition is formulated. Thus, the metes and bounds of the questioned phrase are readily discernable by a person of skill in this art.

The examiner also alleges that the original disclosure does not set forth guidance defining what constitutes a low-medium potency steroidal anti-inflammatory compound. OA, page 3.

However, the examiner has not taken into account that the sub-genus of low to low-medium potency topical steroids required by claim 1 is included within the genus of low to medium potency topical steroid compounds the examiner admits is described in the specification. Furthermore, the examiner has not taken into account the knowledge of a person of skill in the art in making this assertion. That hypothetical person would understand from reading the specification that the topical steroid used in the present technology is one that can be formulated to minimize side effects, yet still be effective. This guidance in the specification serves to define the low to low-medium steroids that are included within the scope of claim 1.

Withdrawal of the rejection is courteously solicited.

Rejections Under 35 U.S.C. § 102 and § 103

Claims 1-3, 7-10 and 13-17 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent Application Publication No. 2003/0232086 to McCadden ("McCadden). Claims 1-3, 7-10, 13 and 17 were rejected under 35 U.S.C. § 102(b) as disclosed by U. S. Patent No. 5,219,877 to Shah *et al.* ("Shah"). Claims 1-3, 7-13 and 17 were rejected under 35 U.S.C. § 102(b) as disclosed by U. S. Patent No. 6,075,056 to Quigley *et al.* ("Quigley").

Claims 4-6, 11 and 12 were rejected under 35 U.S.C. § 103(a) as unpatentable over McCadden. Claims 4-6 were rejected under 35 U.S.C. § 103(a) as unpatentable over Shah. Claims 11 and 12 were rejected under 35 U.S.C. § 103(a) as unpatentable over Quigley. Claims 14-16 were rejected under 35 U.S.C. § 103(a) as unpatentable over Shah in view of U.S. Patent No. 5,686,089 to Mitra ("Mitra"). Claims 14-16 were rejected under 35 U.S.C. § 103(a) as

unpatentable over as unpatentable over Shah in view of U.S. Patent No. 6,444,647 to Robinson ("Robinson").

Analysis

1. Rejections based upon McCadden

Claims 1-3, 7-10 and 13-17 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. 2003/0232086 (McCadden). In addition, claims 4-6, 11 and 12 are rejected under 35 U.S.C. § 103(a) as obvious over McCadden.

Submitted herewith is a declaration under 37 CFR § 1.131 which establishes that the present invention was reduced to practice in this country prior to the earliest priority date claimed by McCadden, September 2, 1999. As seen from Exhibit A of the declaration a patient suffering from a severe form of dermatitis, one of the conditions stated to treatable by the claimed composition at page 3 of the specification, was treated with a combination of EXELDERM® cream (1 % sulconazole nitrate) and WESTCORT® cream (0.2% hydrocortisone valerate), which produced an extremely rapid reduction in redness and swelling. As seen from the Chart, WESTCORT® cream (0.2% hydrocortisone valerate) is a class 5 Lower Mid-strength, or to use applicants terminology, low-medium potency, anti-inflammatory steroid.

Since the present invention was completed prior to the earliest effective date of McCadden, all rejections based upon McCadden should be removed.

Withdrawal of the rejections is courteously solicited.

3. Rejections based upon Shah

a. Claims 1-3, 7-10, 13 and 17 under 35 U.S.C. § 102(b) as anticipated by Shah

Anticipation is an exacting standard. Under 35 U.S.C. § 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim. In re Bond, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990).

Furthermore, in In re Arkley, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972) the court stated "[i]t is to be noted that rejections under 35 USC 103 are proper where the subject matter claimed 'is not identically disclosed or described' (emphasis ours) in 'the prior art,' indicating that rejections under 35 USC 102 are proper only when the claimed subject matter is identically disclosed or described in 'the prior art.'" The court went on to observe that the reference "must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." Id. Finally, the court indicated "[s]uch picking and choosing may be entirely proper in the making of a 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection." Id.

Here, Shah describes a gel formulation comprising an imidazole antifungal agent, either by itself or in combination with a steroid anti-inflammatory agent. Id., column 3, lines 10-16. A

litany of anti-inflammatory steroids is listed at column 3, line 54-column 4, line 2. A preference for mid-potency steroids is expressed at column 4, lines 3-16 of Shah.

While not relied upon by the examiner it is noted that a preferred gel formulation containing 0.2% w/w hydrocortisone-17-valerate is set forth at column 5, lines 30-45 of Shah, as well as in Examples 1, 6 and 7. However, the Chart lists "Westcort Ointment, 0.2%" as containing hydrocortisone valerate and as a Class 4—Mid-Strength composition. The Chart also lists "Westcort cream, 0.2%" as containing hydrocortisone valerate, but as a Class 5—Lower Mid-Strength composition. According to McCadden, the potency of a steroid gel composition is in between an ointment and a cream. Thus, the exemplified gel formulations of Shah are outside the scope of claim 1 since claim 1 only includes low to low-medium potency steroids.

Thus, the examiner's anticipation rejection hinges upon a judicious selection of anti-inflammatory steroids from the litany set forth at column 3, line 54-column 4, line 2 of Shah. Such picking and choosing, at best, bespeaks of an obviousness determination, not an anticipation finding. In re Arkley, supra. Accordingly, Shah does not anticipate claim 1, and by extension, claims 2, 3, 7-13 and 17 that depend directly or indirectly therefrom.

Withdrawal of the rejection is courteously solicited.

b. Claims 4-6 under 35 U.S.C. § 103(a) based upon Shah

Claim 4 requires that the steroidal anti-inflammatory is desonide and the antifungal compound is clotrimazole. Claims 5 and 6 specify how much of these compounds the claimed composition is to contain.

The examiner admits that Shah does not explicitly teach the conjoint use of these two compounds. OA, page 13, third paragraph. However, the examiner concludes that it would have been obvious to select those two specific compounds "so as to impart desired therapeutic antifungal and anti-inflammatory properties to [an] antifungal steroidal composition." OA, paragraph bridging pages 13-14.

Without conceding that it would have been obvious to select desonide and clotrimazole as the active agents in Shah, for the reasons set forth above, the data in Dr. Goldstein's declaration under 37 CFR § 1.132 provides an adequate rebuttal of any *prima facie* case of obviousness that might be supported by this reference.

Withdrawal of the rejection is courteously solicited.

c. Claims 11-12 under 35 U.S.C. § 103(a) based upon Shah and Quigley

Claims 11 and 12 further limit the claimed composition in terms of pH and provide for the presence of a solvent, emollient, humectant, preservative and emulsifier as well as the optional presence of an acid, base or buffering agent to adjust the pH of the composition.

The examiner admits that Shah does not explicitly teach an antifungal steroidal composition that includes such additional compounds. OA, page 14. The examiner relies upon the disclosure of Quigley to make up for these shortcomings in Shah in arriving at his conclusion of obviousness. Id., pages 14-15.

Without conceding that it would have been obvious to combine Shah and Quigley in the manner proposed by the examiner, for the reasons set forth above, the data in Dr. Goldstein's

declaration under 37 CFR § 1.132 provides an adequate rebuttal of any *prima facie* case of obviousness that might be supported by these references.

Withdrawal of the rejection is courteously solicited.

d. Claims 14-16 under 35 U.S.C. § 103(a) based upon Shah and Mitra

Claim 14 sets forth a method of treating a fungal disease by administering the composition of any of claims 1-13 or 17 to a subject in need of such a treatment. Claim 15 specifies that the patient is a child under 10 years old while claim 16 specifies the fungal disease to be treated.

The examiner admits that Shah does not explicitly teach the subject matter of these claims. OA, page 16. The examiner relies upon the disclosure of Mitra to make up for these shortcomings in Shah in arriving at his conclusion of obviousness, Id., pages 16-17.

Without conceding that it would have been obvious to combine Shah and Mitra in the manner proposed by the examiner, for the reasons set forth above, the data in Dr. Goldstein's declaration under 37 CFR § 1.132provides an adequate rebuttal of any *prima facie* case of obviousness that might be supported by these references.

Withdrawal of the rejection is courteously solicited.

e. Claims 14-16 under 35 U.S.C. § 103(a) based upon Shah and Robinson

Claim 14 sets forth a method of treating a fungal disease by administering the composition of any of claims 1-13 or 17 to a subject in need of such a treatment. Claim 15 specifies that the patient is a child under 10 years old while claim 16 specifies the fungal disease to be treated.

The examiner admits that Shah does not explicitly teach the subject matter of these claims. OA, page 18. The examiner relies upon the disclosure of Robinson to make up for these shortcomings in Shah in arriving at his conclusion of obviousness. Id., pages 18-19.

Without conceding that it would have been obvious to combine Shah and Robinson in the manner proposed by the examiner, for the reasons set forth above, the data in Dr. Goldstein's declaration under 37 CFR § 1.132 provides an adequate rebuttal of any *prima facie* case of obviousness that might be supported by these references.

Withdrawal of the rejection is courteously solicited.

3. Rejection based upon Quigley

Claims 1-3, 7-13 and 17 are rejected under 35 U.S.C. § 102(b) as anticipated by Quigley.

Quigley describes topical compositions useful in treating fungal diseases that comprise an antifungal agent and an anti-inflammatory steroid. See, e.g., column 2, line 66-column 3, line 27. The compositions are stated to possess a so-called synergistic effect when the anti-inflammatory steroid is ester bearing. Id. The anti-inflammatory steroids useful in the composition of Quigley are exemplified in a list of steroids classified by potency. Id., column 4, line 52-column 62.

Quigley describes prophetic formulations according to that invention. See Tables A-H and their accompanying text. Quigley also provides Examples 1-11 that are stated to describe various formulations that were prepared. All of the prophetic formulations and those described in the examples either prophetically prefer or are stated to contain betamethasone dipropionate as

the anti-inflammatory steroid. Neither the prophetic formulations nor the exemplified compositions constitute an anticipation of claim 1.

Turning to the prophetic formulations first, it is seen that the steroid may be contained in these formulations in an amount of 0.01-2.5 wt%, preferably 0.01-0.1wt%. Formulations containing betamethasone dipropionate in these amounts are stated by Quigley to range in potency from Class 1 (highest potency) to Class 5 (low-medium potency). Thus, in order to arrive at formulations within the scope of claim 1 from the myriad of the formulations described in the prophetic examples of Quigley would require significant picking and choosing. As set forth in In re Arkley, supra, such picking and choosing is proper only in an obviousness rejection, not an anticipation rejection.

Now turning to the examples of Quigley, it is seen that that the formulations of Examples 1-12 contain 0.064 wt% of betamethasone dipropionate. Example 13 only states that a "test formulation" was used. Based upon the amount of the betamethasone dipropionate, these formulations appear to be in Class 1, 2 and 3 of Quigley and thus are more potent than the compositions of claim1. Even the lotion of Example 10 of Quigley contains 0.064 wt% betamethasone dipropionate. This is equivalent to the amount of betamethasone dipropionate in Lotrisone™ cream that is stated to be very potent at pages 1-2 of the specification. In this regard, note that the betamethasone dipropionate lotion stated by Quigley to be of low-medium potency at column 5, line 30, contained only 0.02% of the steroid. Thus, the examples of Quigley are directed to formulations that are more potent than those of claim 1.

Furthermore, betamethasone is a halogenated steroid. Thus, the prophetic and exemplified formulations of Quigley do not anticipate claim 17 which requires that the steroidal anti-inflammatory is not halogenated.

Withdrawal of the rejection is courteously solicited.

Conclusion

In summary, applicants have demonstrated that the claimed combination unexpectedly provides efficacy and safety, which is neither recognized by nor obvious from the prior art. Allowance of all claims as is therefore earnestly solicited.

Respectfully submitted,

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